K080065

510(k) SUMMARY

OSferion

MAY - 2 2008

November 30th, 2007

1 General Information

- Applicant:

OLYMPUS TERUMO BIOMATERIALS CORP.
34-3 Hirai, Hinode-machi, Nishitama-gun,
Tokyo 190-0182, Japan
Establishment Registration No:
Active; awaiting assignment of registration number

- Official Correspondent:

Laura Storms-Tyler

Regulatory Affairs & Quality Assurance
Olympus America Inc.
3500 Corporate Parkway
PO Box 610
Center Valley PA18034-0610,
Phone: (484) 896-5688
Facsimile: (484) 896-7128
Email:Laura.storms-tyler@olympus.com
Establishment Registration No: 2429304

- Manufacturer:
(Sterilization site)

OLYMPUS TERUMO BIOMATERIALS CORP.
Hinode Factory
34-3 Hirai, Hinode-machi, Nishitama-gun,
Tokyo 190-0182. Japan
Establishment Registration No:
Active; awaiting assignment of registration number

2 Device Identification

- Device Trade Name: **OSferion**
- Common Name: **Bone void filler**
- Regulation Number: **21 CFR 888.3045**
- Regulation Name: **Resorbable calcium salt bone void filler device**
- Regulatory Class: II
- Classification Panel: **Orthopedic**
- Product Code: **MQV**

K060065

3 Predicate Device Information

	Predicate Device		
Device Name:	Synthes (USA) chronOS ™	Vitoss® Scaffold Synthetic Cancellous Bone Void Filler	OSferion
Common Name:	Bone void filler	Bone void filler	Bone void filler
Manufacturer:	Synthes	Orthovita	OLYMPUS TERUMO BIOMATERIALS CORP.
510(k) No.	K043045	K032409	K061499

4 Device Description

OSferion is a white porous material composed of β-tricalcium phosphate(β-TCP). It is intended to fill bony voids or gaps caused by trauma or surgery that are not intrinsic to the stability of the bony structure. OSferion is to be used as a bone replacement material and has properties that allow it to be replaced by autogenous bone after implantation.

The OSferion product range consists of two product types with porosities of 75% and 60%.

Products are supplied in blocks, cylinders, granules and wedges.

5 Indications for Use

OSferion is indicated to be gently packed or placed into bony voids or gaps of the skeletal system (i.e. the extremities, spine and pelvis,) that are not intrinsic to the stability of the bony structure. Following placement in the bony void or gap, the calcium phosphate scaffold resorbs and is replaced with bone during the healing process.

6 Comparison of Technological Characteristics

OSferion is basically identical to the predicate devices in indication for use, and is similar in specifications of the material.

The clinical literatures provided in this submission supports the safety and efficacy of OSferion.

7 Conclusion

When compared to the predicate device, this subject device "OSferion" does not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Olympus Terumo Biomaterials Corporation
% Olympus America Inc.
Ms. Laura Storms-Tyler
3500 Corporate Parkway
P.O. Box 610
Center Valley, PA 18034

MAY - 2 2008

Re: K080065
Trade/Device Name: OSferion
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone filler device
Regulatory Class: II
Product Code: MQV
Dated: April 24, 2008
Received: April 25, 2008

Dear Ms. Storms-Tyler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K080065

Device Name: **OSferion**

Indications for Use:

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Following placement in the bony void or gap, the calcium phosphate scaffold resorbs and is replaced with bone during the healing process.

Prescription Use ✓ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080065